UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION) MDL NO. 1456) Civil Action No. 01-12257-PBS) Subcategory Case No: 03-10643-PBS
THIS DOCUMENT RELATES TO:)) Judge Patti B. Saris
The City of New York, et al.)
v.	,)
Abbott Laboratories, et al.)
)

PLAINTIFFS' REPLY LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO PAR PHARMACEUTICALS COMPANIES, INC. AND PAR PHARMACEUTICAL, INC.

Pursuant to Rule 56.1 of the Local Rules of this Court, plaintiffs hereby submit their Reply Local Rule 56.1 Statement of Undisputed Material Facts As To Par Pharmaceuticals Companies, Inc. and Par Pharmaceutical, Inc. (collectively "PAR").

I. PAR SPECIFIC FACTS

1. The PAR drugs and NDCs that have been examined in connection with this motion are set forth in Exhibit A hereto. This exhibit also sets forth PAR's Published AWPs and WACs for these Drugs and NDCs, any operative Federal Upper Limit ("FUL") and Par's AMPs. The exhibit notes which NDCs are associated with package sizes that set the FUL.

PAR'S RESPONSE TO PARAGRAPH 1: Par does not dispute that Exhibit A to Plaintiffs' Par-Specific Statement purports to (i) list the Par drugs and NDCs that have been examined in connection with Plaintiffs' motion; (ii) set forth published AWPs and WACs for those drugs and NDCs, any operative FUL, and Par's AMPs; and (iii) note which NDCs are associated with the package sizes that set the FUL. Par disputes the data set forth in Exhibit A to the extent that it is not properly supported by evidence in the record. Plaintiffs have cited no evidentiary basis for the data set forth in Exhibit A, as required by Local Rule 56.1. Par further disputes that the alleged facts relating to AWPs are material to plaintiffs' motion, because CMS did not consider AWPs in setting FULs. See Defendants' Local Rule 56.1 Statement of Undisputed Material Facts, filed on May 15, 2009 ("Defs.' 56.1 Stmt."), at ¶ 34 [Master Dkt. No. 6054; Sub. Dkt. No. 55]. Par

further disputes that it provided WACs for its generic products to the pricing compendia as a general practice. *See* Par's Response to Paragraph 12, *infra*.

PLAINTIFFS' REPLY TO STATEMENT #1:

The parties agree that Exhibit A sets forth the Par drugs and NDCs at issue on this motion and the published WACs, AWPs, AMPs and any operative FUL for same.

Par's dispute as to the data in Exhibit A not being properly supported by evidence in the record is baseless. Plaintiffs properly cited Par as the source of the Par AMP data and the First Databank NDDF data file (Alabama Production, FDB-AWP 030785 – 030795) as the source of all other data (*see* Exhibit A at 28), which is the same source cited by Par's expert Dr. Addanki. *See* Affidavit of Dr. Sumanth Addanki dated May 15, 2009 [Dkt# 6056] at Exhibit 2 (identifying "First DataBank (Alabama Production) Data and NDDF (National Drug Data File)TM Documentation Manual (Rev. April 2000)" as a Data source). *See also* Reply Affidavit of Joanne M. Cicala, sworn to June 30, 2009 and submitted in further support of plaintiffs' motion for partial summary judgment at ¶2, which is incorporated herein.

Par disputes that Plaintiffs' Exhibit is accurate and/or complete but offers no evidence in support as required by Rule 56.1. Par's other objections concerning admissibility are likewise baseless and unsubstantiated.

Par's Response that AWP prices are not material to plaintiffs' motion is incorrect. In setting the FUL, CMS considered the published prices from First Databank, Red Book and Medi-Span that were presented in the FULs printouts *See* Declaration of Susan E. Gaston (signed June 15, 2009) ("Gaston Decl.") at ¶3 (statement of general practice). This included AWPs, WACs and Direct Prices. *See id.* at Exhibits A & D (FULs system printouts showing AWP prices). Defendants admit that the published prices presented in the FULs printouts included AWPs. *See* Defendants' Response to Plaintiffs' Local Rule 56.1 Statement of "Undisputed" Facts Applicable

To All Defendants and Statement of Additional Undisputed Material Facts [Dkt#:6117] at ¶9 ("Undisputed").

Responding further, plaintiffs incorporate herein Plaintiffs' Reply to Statement #12.

2. The specific PAR drugs at issue are the Clonazepam .5 MG Tablet, Enalapril Maleate 20 MG Tablet, Metropolol 100 MG Tablet and Ranitidine 150 MG Tablet.

PAR'S RESPONSE TO PARAGRAPH 2: Par does not dispute that Par's Clonazepam .5 MG Tablet is a drug at issue in plaintiffs' motion. Par disputes that the specific Par drugs properly at issue in plaintiffs' motion as to Par include Enalapril Maleate 20 MG Tablet, Metoprolol 100 MG Tablet, or Ranitidine 150 MG Tablet. Plaintiffs have cited no evidentiary basis for this assertion, as required by Local Rule 56.1. Revised Exhibit B to Plaintiffs' Revised First Amended Consolidated Complaint ("RFACC") does not list Metoprolol 100 MG Tablet as a drug at issue in this litigation with respect to Par. See Revised Exhibit B to Plaintiffs' RFACC, at Exhibit B-27 [Master Dkt. No. 4754]. Nor does Revised Exhibit B identify any Par NDC for Enalapril Maleate 20 MG Tablet or Ranitidine 150 MG Tablet as being at issue with respect to Plaintiffs' claims relating to the Federal Upper Limit. See id.; see also Plaintiffs' RFACC, at ¶¶ 15, 146 [Master Dkt. No. 4780] and Revised Exhibit A [Master Dkt. No. 4871].

PLAINTIFFS' REPLY TO STATEMENT #2:

The parties agree that Clonazepam .5 MG Tablet is at issue on this motion. Par's statement that Enalapril Maleate 20 MG Tablet, Metoprolol 100 MG Tablet and Ranitidine 150 MG Tablet are not part of plaintiffs' case against Par is incorrect. Plaintiffs identify Par's Ranitidine 150 MG as an at issue drug at paragraph 608 of their RFACC. See RFACC [Dkt#:4780] at ¶608. Plaintiffs identify Enalapril Maleate 20 MG Tablet (49884059401, 49884059410) and Ranitidine 150 MG Tablet (49884054401, 49884054402, 49884054410) in the Revised Exhibit B for Par. See RFACC - Revised Exhibit B filed on September 29, 2007 (under seal)[Dkt#: 4754]. Responding further, Par's remarks regarding NDCs listed in Exhibit B to plaintiffs' RFACC are irrelevant as it agreed to the nine at-issue Drugs that would be encompassed by the instant motion, and produced relevant data. See CMO 33 [Dkt# 4690-2] (Reply Exhibit A attached hereto) at ¶5.

3. PAR has entered into and executed the federal Medicaid rebate agreement pursuant to 42 U.S.C. § 1396r-8. See Answer of Defendants Par Pharmaceuticals Companies, Inc. and Par Pharmaceutical, Inc. to Plaintiffs' Revised First Amended Consolidated Complaint [Dkt #4827] ("PAR Answer") at ¶132; see also Deposition of PAR Pharmaceuticals 30(b)(6)(Nick DiMaio) dated 5/6/08 ("PAR 30(b)(6)(DiMaio) 5/6/08 Dep.") (Exhibit B) at 27:14-18.

PAR'S RESPONSE TO PARAGRAPH 3: Par does not dispute that Par Pharmaceutical, Inc. has entered into and executed the federal Medicaid Rebate Agreement with the Secretary of Health and Human Services on behalf of all States. Par disputes Paragraph 3 to the extent that it implies that Par Pharmaceutical Companies, Inc. entered into and executed the Rebate Agreement, which was executed on behalf of Par Pharmaceutical, Inc. *See* Declaration of Andrew T. Boone in Support of Par's Response to Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts as to Par ("Boone Decl."), Exh. A (Par's Rebate Agreement).

PLAINTIFFS' REPLY TO STATEMENT #3:

The parties agree that Par Pharmaceuticals, Inc. has entered into and signed the federal Medicaid rebate agreement. Responding further, the PAR Answer speaks for itself and as answered provides that Par Pharmaceutical Co. entered into and signed the federal Medicaid rebate agreement. *See* PAR Answer at ¶132. No further reply is required.

4. PAR participates voluntarily in the state Medicaid programs, including the New York State Medicaid Program. See PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 150:7-13.

<u>PAR'S RESPONSE TO PARAGRAPH 4:</u> Par does not dispute the facts set forth in Paragraph 4.

PLAINTIFFS' REPLY TO STATEMENT #4:

No further response is required.

5. PAR knew that eligibility for reimbursement by Medicaid was a very important issue for its customers and in fact was required to ensure that that its drugs were Medicaid reimbursable. See Deposition of Karen Andrus dated 10/16/07 ("Andrus Dep.")(Exhibit C) at 46:16-48:10; Deposition of Julie Trendowicz dated 4/1/09 ("Trendowicz 4/1/09 Dep.") (Exhibit D) at 165:18-21.

<u>PAR'S RESPONSE TO PARAGRAPH 5:</u> Par does not dispute that Ms. Andrus testified that having Par products listed in the databases was "very important to

[Par's] customers" and that pharmacies could get reimbursed by third-party payors only for products listed in the databases. Except as noted, Par disputes Paragraph 5 to the extent that it mischaracterizes Ms. Andrus's testimony as being specific to Medicaid. In addition, Par does not dispute that Ms. Trendowicz testified that Par's customers required Par to ensure that its drugs were Medicaid reimbursable.

PLAINTIFFS' REPLY TO STATEMENT #5:

The parties agree that Par's customers required Par to ensure that its drugs were Medicaid reimbursable. No further response is required.

6. PAR knew that the AWPs and WACs for PAR drugs were used for reimbursement purposes, including for state Medicaid reimbursement purposes. *See* Trendowicz 4/1/09 Dep. (Exhibit D) at 125:20-126:14, 129:20-131:18; Andrus Dep. (Exhibit C) at 46:16-48:10.

PAR'S RESPONSE TO PARAGRAPH 6: Par disputes that the alleged facts relating to AWPs are material to plaintiffs' motion, because CMS did not consider AWPs in setting FULs. See Defs.' 56.1 Stmt., at ¶ 34. Par further disputes the assertion in Paragraph 6 that it "knew that the AWPs and WACs for [its] drugs were used for reimbursement purposes, including state Medicaid reimbursement purposes." Plaintiffs do not provide an evidentiary basis for this assertion, because the cited testimony does not support this asserted fact. Par does not dispute that it knew that AWPs and WACs could be used as bases for reimbursement, but Par disputes that Par was aware that any particular entity or third-party payor, including state Medicaid agencies, actually used AWPs and WACs in setting reimbursement rates or in reimbursing for any particular Par product. See, e.g., Boone Decl., Exh. B (30(b)(6) Deposition of Nick DiMaio, May 6, 2008 (Vol. I) ("DiMaio 5/6/08 Dep."), at 88:10-12 ("Q. Do you know how FUL is by the federal government? A. No, I don't."); id., Exh. C (30(b)(6) Deposition of Nick DiMaio, July 31, 2008 (Vol. II) ("DiMaio 7/31/08 Dep."), at 543:13-16) ("A. I know that Medicaid reimburses for . . . for Medicaid prescriptions. What I don't know is how they reimburse or how they set that reimbursement."). Par further disputes that it provided WACs for its generic products to the pricing compendia as a general practice. See Par's Response to Paragraph 12, infra.

PLAINTIFFS' REPLY TO STATEMENT #6:

The parties agree that Par knew that its AWPs and WACs could be used as bases for reimbursement. Par cannot reasonable dispute that it knew Medicaid reimbursements were based on AWP. The testimony of Ms. Trendowicz, cited by plaintiffs, includes the following:

Q. (BY MR. WINTER) And I'm not asking you for the precise calculation, but just as a general -general proposition you were aware that Medicare and Medicaid programs in general would use AWP as a benchmark for reimbursement?

MR. DUEFFERT: Objection, form.

A. Yes.

Trendowicz 4/1/09 Dep. (Exhibit D) at 126:8-14

Par cannot reasonably dispute that it knew Medicaid reimbursements were based on WAC. Plaintiffs' cited the following from Ms. Trendowicz:

- Q. Are you familiar or did you know that there was an agency of the federal Department of Health and Human Services, formerly known as HCFA, now known as CMS, or Centers for Medicare and Medicaid services?
 - A. Yes.
 - Q. So you've heard of CMS?
 - A. Yes.
- Q. And did you understand they had something to do with Medicare and Medicaid and running of those programs?
 - A. Yes.
- Q. Okay. So going back to the letter here. "Dear Julie: I recently communicated with you about pending changes in the HCFA reimbursement rate that were to be released on June 1. I am pleased to tell you ... this is now delayed until August 1. In researching the causes for the bad information that HCFA had used to develop their MAC rate, I found that one of the prime causes was inaccurate data. In order to be certain that HCFA makes" an "intelligent" -- "makes intelligent decisions on equitable reimbursement rates, I would ask you to do the following:

Number 1. "Communicate directly with HCFA with your latest information about average wholesale pricing. The information that they currently have access to has many products that are no longer available or are in current short supply." Did I read that accurately?

- A. Yes.
- Q. Number 2. "Request that your wholesale customers update their file immediately. All prices,

both WAC and AWP, need to be current. Additionally, all discontinued products need to be removed from their list. HCFA uses wholesaler information to substantiate pricing. When wholesaler information is not accurate, then HCFA comes to incorrect conclusions." Did I read that accurately?

- A. Yes.
- Q. All right, ma'am. Does this letter refresh your recollection that you had communications with at least one of your customers that would indicate that WAC pricing is pricing that -- that is used in the reimbursement process?
 - A. Yes, I see that now.

Id. at 130:18-131:7

Responding further, Par's Response that AWP prices are not material to plaintiffs' motion is incorrect. In setting the FUL, CMS considered the published prices from First Databank, Red Book and Medi-Span that were presented in the FULs printouts *See* Gaston Decl. at ¶3 (statement of general practice). This included AWPs, WACs and Direct Prices. *See id.* at Exhibits A & D (FULs system printouts showing AWP prices). Defendants admit that the published prices presented in the FULs printouts included AWPs. *See* Defendants' Response to Plaintiffs' Local Rule 56.1 Statement of "Undisputed" Facts Applicable To All Defendants and Statement of Additional Undisputed Material Facts [Dkt#:6117] ("Defs. Common Response") at ¶9.

Responding further, Plaintiffs incorporate Plaintiffs' Reply to Statement #12 herein.

PAR Set and Reported Its AWPs and WACs

7. PAR sets one WAC and one AWP for each of its products. See PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 313:10-12.

<u>PAR'S RESPONSE TO PARAGRAPH 7</u>: Par disputes that the alleged facts relating to AWPs are material to plaintiffs' motion, because CMS did not consider AWPs in setting FULs. *See* Defs.' 56.1 Stmt., at ¶ 34. Notwithstanding the immateriality of the alleged facts relating to AWPs, Par does not dispute that, at

any given time, Par has only one WAC and one AWP for each of its products and that Par sets that WAC and AWP.

PLAINTIFFS' REPLY TO STATEMENT #7:

The parties agree that at any given time, Par has only one WAC and one AWP for each of its products and that Par sets that WAC and AWP.

Par's Response that AWP prices are not material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #6, which is incorporated herein.

8. At all times, from 1997 to 2005, at the time of launch of a new product PAR set an AWP either: (i) at around 10% of the brand AWP if PAR was first to introduce the generic drug; or, (ii) if PAR was not the first, then since AWPs in the generic industry are consistent across the board, then PAR would set the AWP in line with the competition on the market. See PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 42:2-43:4; see also Commonwealth of Mass. v. Mylan, 2008 WL 5650859 (D.Mass)("Mylan") at *5.

<u>PAR'S RESPONSE TO PARAGRAPH 8:</u> Par disputes that the alleged facts relating to AWPs are material to plaintiffs' motion, because CMS did not consider AWPs in setting FULs. *See* Defs.' 56.1 Stmt., at ¶ 34. Par further disputes that plaintiffs have provided an evidentiary basis for the time period prior to Mr. DiMaio's employment with Par in 1998. Except as noted and notwithstanding the immateriality of the alleged facts relating to AWPs, Par does not dispute the facts set forth in Paragraph 8.

PLAINTIFFS' REPLY TO STATEMENT #8:

Par disputes this statement only to the extent that plaintiffs have not provided an evidentiary basis for the time period prior to Mr. DiMaio's employment with Par, in 1998. The time period at issue on this motion is 1997-2005. This means that, even if Par's response has merit (and it does not - *see* following sentence), Par does not dispute that plaintiffs have an evidentiary basis for all but 1 year of the operative time period. Responding further, it cannot reasonably be disputed that plaintiffs have an evidentiary basis for 1997 given that Mr. DiMaio was designated by Par as its Rule 30(b)(6) witness the entire period at issue and Mr. DiMaio expressly testified that he was appearing pursuant to plaintiffs' notice as representative for Par

without qualification as to time. *See* Reply Exhibit A (attached hereto)(Excerpts of PAR 30(b)(6)(DiMaio) 5/6/08 Dep.) at 202:2-203:1; *id.* at 203:2-4 (Par counsel stating, "Par has designated [Mr. DiMaio] to address all the topics in this notice, for the record."); *see also Briddell v. Saint Gobain Abrasives, Inc.*, 233 F.R.D. 57, 60 (D. Mass. 2005) (Even if witness was not employed by company during the relevant time period, witness must either educate himself or herself or company must designate another individual to testify); *Calzaturficio S.C.A.R.P.A. s.p.a. v. Fabiano Shoe Co., Inc.*, 201 F.R.D. 33, 36-37 (D. Mass. 2001) (rule 30(b)(6) witness is obligated to be knowledgeable about matters that go beyond the witness's personal knowledge or matters the witness was personally involved in).

Par's Response that AWP prices are not material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #6, which is incorporated herein.

9. Nick DiMaio testified that AWPs for PAR generic products are set at the product launch and PAR will only "manage our AWPs so they compete or they're comparable with our competitive AWPs, so you'll find our AWPs typically match most all the competitors." See PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit 1) at 132:14-1336. When lower prices are offered to pharmacies, PAR does not typically lower the AWP because "there's no financial incentive for [PAR] to manage AWP in that way." Id. at 133:8-134:2.

PAR'S RESPONSE TO PARAGRAPH 9: Par disputes that the alleged facts relating to AWPs are material to plaintiffs' motion, because CMS did not consider AWPs in setting FULs. See Defs.' 56.1 Stmt., at ¶ 34. Notwithstanding the immateriality of the alleged facts relating to AWPs, Par does not dispute that Mr. DiMaio's testimony is consistent with the first sentence of Paragraph 9. Par disputes the second sentence of Paragraph 9 to the extent that it mischaracterizes Mr. DiMaio's testimony and Par's reason for not lowering its AWPs as lower prices were offered to customers. As Mr. DiMaio testified: Q. Does Par lower the AWP to match the new lower prices that are given to retail pharmacies? A. Yeah, that's -- we typically don't -- there's no financial incentive for us to manage AWP in that way. So – and typically what happens, then, more competitors come in, limits are established so the AWP, it doesn't matter where it was because reimbursement isn't based on it. So that's why we typically don't manage it. It's typically set and it stands alone and we move on to contract negotiated pricing. Boone Decl., Exh. B (DiMaio 5/6/08 Dep. at 133:14-134:2).

PLAINTIFFS' REPLY TO STATEMENT #9:

Par offers no meaningful dispute to Mr. DiMaio's testimony. Plaintiffs maintain that there was no mischaracterization of the testimony, to wit: that there is no financial incentive to Par to lower AWPs when it has offered new lower prices to pharmacies. Plaintiffs dispute Par's added testimony of Mr. DiMaio to the extent it seeks to establish that AWPs are not used for reimbursement for Par generic drugs. *See* Plaintiff's Reply to Statement #6, which is incorporated herein.

Par's Response that AWP prices are not material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #6, which is incorporated herein.

10. At all times, from 1997 to 2005, at the time of launch of a new product PAR set a WAC for each drug it sold typically at 20% of the WAC for the bioequivalent branded drug. As competition increases in the generic market, PAR quickly lowered its WAC prices to stay competitive. See Deposition of PAR Pharmaceuticals 30(b)(6)(Nick DiMaio) dated 8/16/07 ("PAR 30(b)(6)(DiMaio) 8/16/07 Dep.") (Exhibit E) at 153:18-154:12; see also Mylan, 2008 WL 5650859 at *5.

PAR'S RESPONSE TO PARAGRAPH 10: Par disputes that plaintiffs have provided an evidentiary basis for the time period prior to Mr. DiMaio's employment with Par in 1998. Par does not dispute that, after that time and through 2005, it often initially set its WAC prices for newly-launched drugs at a discount of approximately twenty percent to the bioequivalent branded drug's WAC. Par likewise does not dispute that competition in the generic drug market quickly drove WAC prices down.

PLAINTIFFS' REPLY TO STATEMENT #10:

Par disputes this statement only to the extent that plaintiffs have not provided an evidentiary basis for the time period prior to Mr. DiMaio's employment with Par, in 1998. The time period at issue on this motion is 1997-2005. This means that, even if Par's response has merit (and it does not - *see* following sentence), Par does not dispute that plaintiffs have an evidentiary basis for all but 1 year of the operative time period. Responding further, it cannot reasonably be disputed that plaintiffs have an evidentiary basis for 1997 given that Mr. DiMaio

was designated by Par as its Rule 30(b)(6) witness the entire period at issue and Mr. DiMaio expressly testified that he was appearing pursuant to plaintiffs' notice as representative for Par without qualification as to time. *See* Reply Exhibit A (attached hereto) (Excerpts of PAR 30(b)(6)(DiMaio) 5/6/08 Dep.) at 202:2-203:1; *id.* at 203:2-4 (Par counsel stating, "Par has designated [Mr. DiMaio] to address all the topics in this notice, for the record."); *see also Briddell v. Saint Gobain Abrasives, Inc.*, 233 F.R.D. 57, 60 (D. Mass. 2005) (Even if witness was not employed by company during the relevant time period, witness must either educate himself or herself or company must designate another individual to testify); *Calzaturficio S.C.A.R.P.A. s.p.a. v. Fabiano Shoe Co., Inc.*, 201 F.R.D. 33, 36-37 (D. Mass. 2001) (rule 30(b)(6) witness is obligated to be knowledgeable about matters that go beyond the witness's personal knowledge or matters the witness was personally involved in).

11. At all times, from 1997 to 2005, PAR provided the AWP for its generic drugs to all three of the national pricing compendia – First DataBank, RedBook and Medi-Span. See Andrus Dep. (Exhibit C) at 45:11-46:8; see also PAR Answer [Dkt #4827] at ¶10. PAR expected the AWPs it submits to the compendia like First Databank to be published. See PAR 30(b)(6)(DiMaio) 5/6/08 (Exhibit B) at 162:7-21.

PAR'S RESPONSE TO PARAGRAPH 11: Par disputes that the alleged facts relating to AWPs are material to plaintiffs' motion, because CMS did not consider AWPs in setting FULs. See Defs.' 56.1 Stmt., at ¶ 34. Par further disputes that plaintiffs have provided an evidentiary basis for the time period prior to Ms. Andrus's and Mr. DiMaio's employment with Par in 1998. Except as noted and notwithstanding the immateriality of the alleged facts relating to AWPs, Par does not dispute that, after that time and through 2005, Par submitted the AWPs for its generic products to First DataBank, RedBook, and Medi-Span, and that Par expected those AWPs to be published by the compendia.

PLAINTIFFS' REPLY TO STATEMENT #11:

The parties agree that from 1998 through 2005, at a minimum, Par submitted the AWPs for its generic products to First DataBank, RedBook, and Medi-Span, and that Par expected those AWPs to be published by the compendia. Par's objection to record evidence for 1997 is

baseless. *See* Plaintiffs' Reply to Statement #10, which is incorporated herein. Par's Response that AWP prices are not material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #6 which is incorporated herein.

12. PAR maintains that it does not directly report a WAC for each PAR generic drug to the pricing compendia; however, PAR knew that the national pricing compendia collected and reported WAC prices for PAR drugs. See Andrus Dep. (Exhibit C) at 99:4-13; see also Mylan, 2008 WL 5650859 at *16-17.

PAR'S RESPONSE TO PARAGRAPH 12: Par does not dispute that, as a general practice, it does not and did not supply WACs for any of its generic products to the pricing compendia. Nor does Par dispute that it discovered on one or more occasions that the pricing compendia reported in their databases WAC prices for certain of its drugs. However, Par disputes that it "knew" that the national pricing compendia "collected and reported WAC prices" for Par drugs, and disputes any inference that Par approved of any compendium's collection or use of such data. As Ms. Andrus testified: A. We did not provide First DataBank with our WACs, so we did not want them listed at all. We cannot control any of the databases' sources for our information. The fact that they might be able to get it from one of our customers is not us providing them with that information. And nor was it arranged that way. Boone Decl., Exh. D (Deposition of Karen Andrus, October 16, 2007 ("Andrus Dep."), at 108:6-12).

Ms. Andrus served as Par's primary contact with the national pricing compendia and is the person most knowledgeable about Par's communications with those compendia. See id., Exh. D (Andrus Dep. at 45:20-46:3); id., Exh. D (Andrus Dep. at 61:4-6); id., Exh. B (DiMaio 5/6/08 Dep. at 165:20-166:5) (testifying that correspondence with First DataBank would come from Ms. Andrus's group). Whenever Ms. Andrus learned that the pricing compendia had populated a field with data purporting to be Par's WAC prices, Ms. Andrus would direct the compendia to remove Par's WAC prices or "zero out" the data. See, e.g., id., Exh. D (Andrus Dep. at 59:21-60:4) (confirming Par's policy "to zero out or remove the WACs whenever it found out that one of the reporting services, whether it be Red Book, First DataBank or Medi-Span, was reporting WACs for Par products"); see also, e.g., id., Exh. D (Andrus Dep. at 52:3-5)("And we also had [Red Book] remove our WAC pricing from any of their databases so that they would not publish it or put it on any other source."); id., Exh. D (Andrus Dep. at 100:13-21) ("I recall seeing printouts from the databases with a WAC price listed for us, yes. And I recall crossing them out and asking them to zero them out."); id., Exh. D (Andrus Dep. at 111:17-21) ("It was consistent with our policy for the whole -- for the databases not to have anything populated in the WAC price list. And we did what we could in order to get them to zero those prices out.").

PLAINTIFFS' REPLY TO STATEMENT #12:

Par cannot reasonably dispute that it knew that the national pricing compendia collected and reported WAC prices for PAR drugs. Par's 30(b)(6) witness Mr. DiMaio, Executive Vice President of Sales & Marketing for Par, testified:

- Q. Were those WAC prices ever published?
- A. There's -- pricing -- I am not sure. We subscribe to a service of pricing and can get history on WAC pricing, AWP. WAC pricing is populated in that service.
 - Q. Who do you purchase that service from?
- A. It was a -- one of the pricing service -- Medi-Span or First DataBank. One of them.
- Q. In fact, Par subscribed to First DataBank service; correct?
- A. The hard copy. I believe it was the hard copy.
- Q. So if you saw a WAC in a First DataBank database, you would ask First DataBank to zero it out or get rid of it; correct?
- A. No. We would never influence getting rid of WAC pricing because they publish WAC pricing. We knew that they were doing that. We never told them to eliminate WAC pricing.

PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 163:13-164:9 (emphasis added).

Nor can Par reasonably insist that its "policy" of "zeroing out WACs" was followed. The record evidence is that Par did not zero out WACs (*see* Plaintiffs' Reply to Statement #13) and that, on occasion at least, Par affirmatively supplied WACs. *See* Plaintiffs' Rule 56.1 Statement as to PAR Exhibit B (PAR 30(b)(6)(DiMaio) 5/6/08 Dep. at 354:16-355:19) & Exhibit F (PAR 30(b)(6)(DiMaio) 5/6/08 Dep. Exhibit 82 (5/27/03 email from Marissa Caputo (PAR) to Theresa Castro (FDB))).

After not disputing that "it discovered on one or more occasions that the pricing compendia reported in their databases WAC prices for certain of its drugs", Par disputing that it

"knew" that the national pricing compendia "collected and reported WAC prices" for Par drugs is a distinction without a difference. Par does not dispute that Mr. DiMaio testified that First Databank "essentially [] had our WAC pricing anyhow." *See* Plaintiffs' Reply to Statement #13, which is incorporated herein.

13. Karen Andrus testified that PAR provided WACs to any customer or entity that was not a reporting service. *See id.* at 52:18-22, 58:15-59:8. Nick DiMaio testified that PAR did not provide WAC pricing to First Databank because First Databank already had it anyway so there was no reason to provide it. *See* PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 84:13-85:12. However, according to a document produced by First Databank, on May 27, 2003 Marissa Caputo of PAR emailed to Theresa Castro of First DataBank the WAC pricing for PAR's generic drug Torsemide. *See* PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 354:16-355:19; Exhibit F (PAR 30(b)(6)(DiMaio) 5/6/08 Dep. Exhibit 82 (5/27/03 email from Marissa Caputo (PAR) to Theresa Castro (FDB))).

PAR'S RESPONSE TO PARAGRAPH 13: Par does not dispute that Ms. Andrus testified that Par provided its WACs to "[p]retty much anybody that asked, other than the databases." Boone Decl., Exh. D (Andrus Dep. at 52:20-22). Nor does Par dispute that Mr. DiMaio testified that "essentially they had our WAC pricing anyhow." Id., Exh. B (DiMaio 5/6/08 Dep. at 85:3-6). However, Par disputes plaintiffs' characterization of Ms. Andrus's and Mr. DiMaio's testimony to the extent that Paragraph 13 suggests that Par would have supplied WAC prices to the compendia had those compendia not otherwise had access to WACs for Par products. As Mr. DiMaio testified: "A. My understanding is they needed a price to load the product. Q. But when they ask you for WACs, you refused; correct? A. There was -- yes. There was no reason to do that since we were already supplying AWP and our products were being loaded." Id., Exh. B (DiMaio 5/6/08 Dep. at 84:11-17). Ms. Andrus has also testified regarding Par's concern that, if Par did choose to supply its WAC prices to the compendia, competing manufacturers could use the published WACs in an effort to determine Par's contract pricing. See id., Exh. D (Andrus Dep. at 125:15-19). Moreover, Par's policy was to request that the pricing compendia remove or "zero out" WAC pricing whenever Par learned that the compendia were populating their databases with purported WAC prices for Par products. See Par's Response to Paragraph 12, supra.

Par further disputes that WAC prices for Torsemide, which is not a drug at issue in plaintiffs' motion (or in this litigation as to Par), are material to plaintiffs' motion. Par further disputes any inference that Par communicated to First DataBank or other pricing compendia WAC prices for its generic products as a general practice. Ms. Andrus served as Par's primary contact with the pricing compendia and is the person most knowledgeable about Par's communications with those compendia. *See* Par's Response to Paragraph 12, *supra*. As Ms. Andrus testified, Par did not provide WAC prices to the pricing compendia and, when Par

discovered that those compendia were populating their databases with purported WACs for Par products, Par would request that the compendia remove or "zero out" those WACs. *See id.* Ms. Andrus also testified: (Q. You said earlier in your prior answer that during the time that Par did not provide a WAC, it's your understanding that Par, while you were there, never did provide a WAC; correct? A. Yes. If any WAC was provided, it would have been an error. And it would have been a mistake. But it was – it was not anything that normally we -- we made a mistake on.) Boone Decl., Exh. D (Andrus Dep. at 93:16-94:1).

PLAINTIFFS' REPLY TO STATEMENT #13:

Par only disputes "plaintiffs' characterization of Ms. Andrus's and Mr. DiMaio's testimony to the extent that Statement #13 suggests that Par would have supplied WAC prices to the compendia had those compendia not otherwise had access to WACs for Par products." This means that Par does not dispute the Statement.

Plaintiffs object to and dispute the additional citations by Par to the extent that they are offered to establish as fact that any Par "policy" to not report WAC and to have the compendia remove its WAC prices trumps Par's actual practices as established by the record evidence on this motion. The record evidence shows that Par's actual practice was contrary of any such "policy". *See* Plaintiffs' Reply to Statement #12, which is incorporated herein.

Plaintiffs do not maintain that Torsimide is a drug at issue on this motion or in this case, however, the record evidence showing that Par provided WAC pricing for this drug to FDB is material because establishes as fact that Par's practice was other than its "policy". It cannot reasonably be disputed that Par provided WACs to First Databank in direct contradiction to Par's stated "policy".

14. PAR knew and controlled the AWPs and WACs for its drugs that were published by the national pricing compendia. PAR would periodically get National Drug Data File Product Update Reports from First Databank showing AWP and WAC (WHLNET) pricing for PAR drugs and requesting that PAR verify and update its published pricing. See Andrus Dep. (Exhibit C) at 99:4-13, 100:3-21, 111:14-113:22; Exhibit G (Andrus Dep. Exhibit 8 (email with attachment from Karen Andrus to Nick

DiMaio and Marissa Caputo dated 9/14/04 addressing an email string between First Databank and Cardinal concerning PAR's published AWPs and WACs for its drugs.)).

PAR'S RESPONSE TO PARAGRAPH 14: Par disputes that the alleged facts relating to AWPs are material to plaintiffs' motion, because CMS did not consider AWPs in setting FULs. See Defs.' 56.1 Stmt., at ¶ 34. Notwithstanding the immateriality of the alleged facts relating to AWPs, Par does not dispute that it (i) set the AWPs and WACs for its drugs; (ii) provided AWPs for its drugs to the pricing compendia; and (iii) expected that the pricing compendia would publish those AWPs. Except as noted, Par disputes that it "knew and controlled the AWPs and WACs for its drugs that were published by the national pricing compendia." Plaintiffs have not provided any evidentiary basis for this assertion, as required by Local Rule 56.1. As a general practice, Par did not provide WAC prices to the pricing compendia and, when Par learned that those compendia were populating their databases with purported WACs for Par products, Par would request that the compendia remove or "zero out" those WACs. See Par's Response to Paragraph 12, supra.

With respect to the second sentence of Paragraph 14 and notwithstanding the immateriality of the alleged facts relating to AWPs, Par does not dispute that it received one or more National Drug Data File Product Update Reports from First DataBank showing AWP and WHLNET pricing for Par products and requesting that Par verify and update its pricing, but Par disputes that it received such reports "periodically." *See, e.g.*, Boone Decl., Exh. D (Andrus Dep. at 60:12-15) (testifying that First DataBank would send material on Par's pricing only when First DataBank or Par "had a question"). Par further disputes any suggestion or inference that the "WHLNET" data listed by First DataBank accurately depicted any Par WAC prices. As Ms. Andrus testified: "I recall more situations where the databases would have incorrect WACs listed or incorrect information listed, and that would prompt me to try to have the database zero out that information." *Id.*, Exh. D (Andrus Dep. at 132:19-133:1).

PLAINTIFFS' REPLY TO STATEMENT #14:

The parties agree that Par (i) set the AWPs and WACs for its drugs; (ii) provided AWPs for its drugs to the pricing compendia; and (iii) expected that the pricing compendia would publish those AWPs. Par's Response that AWP prices are not material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #1 which is incorporated herein.

The parties further agree that Par received one or more National Drug Data File Product Update Reports from First DataBank showing AWP and WHLNET pricing for Par products and requesting that Par verify and update its pricing.

Par contends that plaintiffs have not established an evidentiary basis that Par "knew and controlled the AWPs and WACs for its drugs that were published by the national pricing compendia." This is incorrect. The record evidence shows that Par "knew" its AWPs and WACs were published (*see* PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 84:13-85:12;; *see also* email dated September 14, 2004 from Karen Andrus to Marissa Caputo stating, "For our information only, please let us know whether FDB has any of our WACs listed incorrectly." Exhibit G to Plaintiffs' Rule 56.1 Statement as to Par) and controlled their publication *See* Plaintiffs' Reply to Statements #13 and #15, which are incorporated herein.

Par disputes plaintiffs use of the word of "periodically" but the record evidence shows that Par did receive the National Drug Data File Product Update Reports from First Databank periodically. *See* Andrus Dep. (Exhibit C) at 99:4-13, 100:3-21, 111:14-113:22.

15. PAR responded to the Product Listing Verifications relied upon by Redbook requesting PAR to verify the accuracy of the AWPs and WACs for its drugs that Redbook published with any changes or corrections. *See* Deposition of Kristen Minne (Redbook) dated 11/18/08 ("Minne 11/18/09 Dep.") (Exhibit H) at 303:10-305:16; Exhibit I (Minne 11/18/08 Dep. Exhibit 67 (Redbook Product Listing Verification for PAR signed by Marissa Caputo on 9/11/03)). The Product Listing Verification signed by Marissa Caputo on 9/11/03, shows that PAR did not instruct Redbook to not publish the WACs prices listed or that the WAC should be set at \$0.00. *See id*.

PAR'S RESPONSE TO PARAGRAPH 15: Par disputes that the alleged facts relating to AWPs are material to plaintiffs' motion, because CMS did not consider AWPs in setting FULs. See Defs.' 56.1 Stmt., at ¶ 34. Notwithstanding the immateriality of the alleged facts relating to AWPs, Par does not dispute that (i) Par responded to one or more Product Listing Verifications received from Redbook and (ii) Ms. Minne of Redbook testified that Redbook relied on Par to verify the accuracy of pricing for Par's products. Par also does not dispute that attached as Exhibit I to Plaintiffs' Par-Specific Statement is a Red Book® Product Listing Verification signed by Marissa Caputo and dated either 9/11/03 or 9/12/03, but Par disputes that the document does not instruct Redbook not to publish the WAC prices listed therein or that the WAC should be set at \$0.00. With respect to Par's Clonazepam 0.5 mg Tablet, the only drug at issue in plaintiffs' motion as to Par, there is a notation in Exhibit I that the drug has been "discontinued." Par further disputes that this document is representative of Par's general business practices with respect to responding to requests by Redbook to

verify AWP and WAC prices. See Par's Response to Paragraphs 12 & 13, supra.

PLAINTIFFS' REPLY TO STATEMENT #15:

The parties agree that (i) Par responded to one or more Product Listing Verifications received from Redbook, (ii) Ms. Minne of Redbook testified that Redbook relied on Par to verify the accuracy of pricing for Par's products; and, (iii) attached as Exhibit I to Plaintiffs' Par-Specific Statement is a Red Book® Product Listing Verification signed by Marissa Caputo and dated either 9/11/03 or 9/12/03. Responding further, Exhibit I speaks for itself and shows that there are no instructions to change any WAC prices but there are other notations unrelated to WAC prices. Exhibit I is also further record evidence that Par did not follow its alleged "policy" regarding the publication of its WAC pricing.

Par's Response that AWP prices are not material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #6 which is incorporated herein.

Responding further, Par's Clonazepam 0.5 mg tablet is not the only Par drug at issue on this motion. *See* Plaintiffs' Reply to Statement #2, which is incorporated herein.

16. PAR subscribed to First Databank Price Alert service to monitor both its published prices and that of its competitors as well as the HCFS MACs or Federal Upper Limits (FUL). See PAR Pharmaceuticals 30(b)(6)(Nick DiMaio) dated 7/31/08 ("PAR 30(b)(6)(DiMaio) 7/31/08 Dep.") (Exhibit J) at 398:9-399:22. According to Nick DiMaio, PAR knew WACs were being published, but PAR "never told them to eliminate WAC pricing." See PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 164:3-9.

<u>PAR'S RESPONSE TO PARAGRAPH 16</u>: Par disputes Paragraph 16. Specifically, Par responds as follows:

First, Par does not dispute that it subscribed to Price Alert, but Par disputes plaintiffs' characterization of Par's motivation for doing so. As Mr. DiMaio testified: "A. We would -- several reasons. It would identify players in each of our generic categories, who actually was marketing products. It was a good way for us to identify our competition. When new people entered the market, we knew that their product was active by way of their introduction into the -- into the publication. Q. Beyond tracking your competitors' activities, what other activities, if any, did Price Alert have? A. From a business perspective, it didn't impact on business practices. It was just information on NDC numbers,

descriptions, HCFA MACS, when they were published; and I believe it also published AWP. So it was a reference guide for those -- those four items." Boone Decl., Exh. C (DiMaio 7/31/08 Dep. at 399:7-22).

Second, Par does not dispute that, beginning sometime in 2004 or 2005, Mr. DiMaio learned on one or more occasions that purported WAC prices for certain Par products were being published in Analy\$ource, but Par otherwise disputes plaintiffs' characterization of Mr. DiMaio's testimony. See id., Exh. E (30(b)(6) Deposition of Nick DiMaio, August 16, 2007, at 252:19-253:18). In addition, Par does not dispute that Mr. DiMaio testified that "[w]e never told them to eliminate WAC pricing," but Par disputes plaintiffs' characterization of Mr. DiMaio's testimony to the extent Paragraph 16 suggests that Par did not request that First DataBank remove or "zero out" the published WAC prices for its products or that Par otherwise authorized First DataBank to publish WAC prices for its products. See Par's Response to Paragraph 12, supra.

PLAINTIFFS' REPLY TO STATEMENT #16:

The Parties agree that Mr. DiMaio testified that Par "never told [First DataBank] to eliminate WAC pricing." The parties further agree that Par subscribed to Price Alert. The remainder of Par's response is disputed (*see* Plaintiffs' Reply to Statement #12, which is incorporated herein) and irrelevant. No further response is required.

17. PAR maintained the view that if it did not send its WAC to the national pricing compendia that "PAR is not responsible for what FUL/MAC HCFA sets based on WACs." See Exhibit K (Andrus Dep. Exhibit 20 (email from Andrus to DiMaio dated 9/25/03)).

PAR'S RESPONSE TO PARAGRAPH 17: Par does not dispute that as a general practice it did not send WACs for its products to the national pricing compendia, and does not dispute that Ms. Andrus wrote that "Par is not responsible for what FUL/MAC HCFA sets based on WACs?," but Par disputes Paragraph 17 to the extent that it mischaracterizes Ms. Andrus's email. See Boone Decl., Exh. D (Andrus Dep. at 174:8-18) (testifying that she was "questioning Nick to understand what the issue was"). Par further disputes Paragraph 17 to the extent that it mischaracterizes Par's motivation for not providing WAC prices to the compendia. See Par's Response to Paragraph 13, supra. Par further disputes Paragraph 17 to the extent that it suggests that Par knew how CMS was, in fact, setting FULs. See Par's Response to Paragraph 6, supra.

PLAINTIFFS' REPLY TO STATEMENT #17:

Plaintiffs stand by the Statement. The record evidence speaks for itself and

clearly states:

"Hi Nick, Thoughts on the Commonwealth of MA.... Par does not send our WACs to First Databank (or other databases). We do send them to TX Medicaid. Therefore, Par is not responsible for what FUL/MAC HCFA sets based on WACs? Also, our current WAC on those items are not artificially inflated. Wasn't Ranitidine already MACs when Par entered the Market? I thought we came late."

Responding further, plaintiffs incorporate their replies to Statements#13 & # 6, herein. No further reply is required.

PAR's Published AWPs and WACs had No Relationship to Actual Prices

18. None of PAR's customers ever purchased PAR drugs at AWP, and in fact its customers purchased PAR drugs at prices far below AWP. See Trendowicz 4/1/09 Dep. (Exhibit D) at 79:7-15.

PAR'S RESPONSE TO PARAGRAPH 18: Par disputes that the alleged facts relating to AWPs are material to plaintiffs' motion, because CMS did not consider AWPs in setting FULs. See Defs.' 56.1 Stmt., at ¶ 34. Notwithstanding the immateriality of the alleged facts relating to AWPs, Par does not dispute the facts set forth in Paragraph 18.

PLAINTIFFS' REPLY TO STATEMENT #18:

The parties agree that none of Par's customers ever purchased Par drugs at AWP and in fact purchased Par drugs at prices far below AWP. Par's Response that AWP prices are not material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #1 which is incorporated herein.

No further reply is required.

19. PAR knew that prices for its generic drugs typically decreased over time and that if PAR kept its AWPs unchanged that its customers' profit spread would increase with the price erosion. See PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 182:17-184:15; Exhibit L (PAR 30(b)(6)(DiMaio) 5/6/08 Dep. Exhibit 40 (1/18/05 email from Mike Burton (PAR) to Charles Burnett (Costco) stating, "Generally our AWP does not follow pricing down, so you (sic) spread will increase with erosion.")).

PAR'S RESPONSE TO PARAGRAPH 19: Par disputes that the alleged facts relating to AWPs are material to plaintiffs' motion, because CMS did not consider AWPs in setting FULs. See Defs.' 56.1 Stmt., at ¶ 34. In addition, Par does not

dispute that the prices for its generic drugs typically decreased over time, but Par disputes plaintiffs' characterization of Mr. DiMaio's testimony and disputes that Par "knew . . . that if PAR kept its AWPs unchanged that its customers' profit spread would increase with the price erosion." As Mr. DiMaio testified: "Q. . . . Is it a typical occurrence for your retail customers like Costco, that if you introduce a new generic, that where there's price erosion, that there will be an increase in margin because of the spread? *** A. No, the price can decrease. Again, when you speak about margin, typically what happens, you know, there's some reimbursement at that point. There's more competition is coming in. The price is going down. And there's a limit. I mean plans will only reimburse so much so the AWP doesn't really matter because plans don't look at AWP or they'll come up with a MAC of their own. A lot of insurance plans now are not using AWP. So the margin, that's why we don't comment on margin, because there's too many plans and too many reimbursement issues just to say that AWP can impact margin." Boone Decl., Exh. B (DiMaio 5/6/08 Dep. at 184:16-185:15).

PLAINTIFFS' REPLY TO STATEMENT #19:

Par's Response that AWP prices are not material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #1 which is incorporated herein.

The parties agree that the prices for Par's generic drugs typically decreased over time. Responding further, the record evidence clearly supports plaintiffs' statement and speaks for itself. *See* January 18, 2005 email from Mike Burton (PAR) to Charles Burnett (Costco) stating, "Generally our AWP does not follow pricing down, so you (sic) spread will increase with erosion". (Exhibit L). Responding further, the testimony of Mr. DiMaio cited by Par is not responsive to plaintiffs' statement. If anything, it only establishes that there is a limit to the increased margin created by price erosion.

20. PAR initially invoices the three national wholesalers (Cardinal Health, AmerisourceBergen and McKesson) for the purchase of PAR products at WAC but thereafter they receive chargebacks, discounts, rebates, billbacks and other incentives from PAR that get the wholesalers to their net cost. See PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 49:3-51:10.

<u>PAR'S RESPONSE TO PARAGRAPH 20</u>: Par does not dispute that Par invoices the three national wholesalers at WAC for the purchase of Par products at WAC, and that oftentimes those wholesalers thereafter receive discounts and other reductions in price that impact the wholesalers' net costs. However, Par

disputes that a chargeback is a form of incentive to wholesalers and further disputes that a wholesaler necessarily receives a chargeback in connection with every sales transaction. *See* Boone Decl., Exh. B (DiMaio 5/6/08 Dep. at 50:9-16) (testifying that the "chargeback is used just to make [the wholesalers] whole" and that, in certain instances, wholesalers do not receive a chargeback). Par further disputes Paragraph 20 to the extent that it suggests that a wholesaler is necessarily entitled to a rebate or other reduction in price under the terms of every sales contract with Par. Plaintiffs' have not provided an evidentiary basis for any such assertion, because the cited testimony does not support that asserted fact.

PLAINTIFFS' REPLY TO STATEMENT #20:

The parties agree that Par invoices the three national wholesalers for the purchase of Par products at WAC, and that oftentimes those wholesalers thereafter receive discounts and other reductions in price that impact the wholesalers' net costs.

Responding further, plaintiffs' citation of Par 30(b)(6) witness Mr. DiMaio's testimony that chargebacks reduce the wholesaler's net purchase amount speaks for itself:

Q. I want to be fair, Mr. DiMaio. Before I show you the next exhibit, I want to ask you once again whether or not you will tell this jury under oath that Par sells any drugs to wholesalers at WAC being the net cost that the wholesaler pays.

A. I think what we have to -- what you have to say is they purchase at WAC. After chargebacks, that is ultimately, then, if you want to look at that as their net purchase, that would be defined as their net purchase. Now not every product, though, and every sale has chargebacks.

PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 50:17-51:10.

21. At least 90% of PAR sales are contract sales that are below WAC and are subject to chargebacks. See PAR 30(b)(6)(DiMaio) 5/6/08 (Exhibit B) at 53:8-54:2, 81:4-8; PAR 30(b)(6)(DiMaio) 8/16/07 Dep. (Exhibit E) at 179:16-22.

<u>PAR'S RESPONSE TO PARAGRAPH 21</u>: Par disputes Paragraph 21. Plaintiffs do not provide an evidentiary basis for the facts asserted in Paragraph 21, because

the cited testimony does not support those asserted facts. Nevertheless, Par does not dispute that Mr. DiMaio testified that 90% of Par's generic sales are pursuant to a contract and that sales made through wholesalers pursuant to a contract are subject to a chargeback. *See* Boone Decl., Exh. B (DiMaio 5/6/08 Dep. at 53:16-54:2) (testifying that he did not have the "hard facts" at hand).

PLAINTIFFS' REPLY TO STATEMENT #21:

The parties agree that Par's corporate designee testified that 90% of Par's generic sales are pursuant to a contract and that sales made through wholesalers pursuant to a contract are subject to a chargeback.

Responding further, plaintiffs incorporate Plaintiffs' Reply to Statement #20 herein. No further reply is required.

22. PAR also sold its drugs to distributors, which differed from wholesalers in that the distributor only carried generic drugs and the wholesalers carried both brand and generic drugs. See Tendowicz 4/1/09 Dep. (Exhibit D) at 38:3-11. PAR maintained different pricing for distributors and wholesalers and depending on the product the distributor would get the better pricing. Id. at 38:12-39:7. PAR does not invoice distributors at WAC but instead at a direct or contract price that would typically be lower than the WAC for the drug. Id. at 75:10-25.

PAR'S RESPONSE TO PARAGRAPH 22: Par does not dispute that Ms. Trendowicz's testimony is consistent with the facts set forth in Paragraph 22, but Par disputes Paragraph 22 to the extent that it mischaracterizes Ms. Trendowicz's testimony as support for any asserted facts other than her general beliefs about the practices of certain Par customers. Par does not dispute that it typically maintained different price points for different Par customers that depended on, among other factors, the product. Par likewise does not dispute that the prices at which it invoiced the customers to whom Ms. Trendowicz referred as "distributors" were typically lower than WAC.

PLAINTIFFS' REPLY TO STATEMENT #22:

The parties agree that Ms. Trendowicz's testimony is consistent with the facts set forth in the Statement. It cannot reasonably be disputed that Ms. Trendowicz, as VP for National Accounts (1998) and Vice President of Sales (1999-2007), has sufficient experience and personal knowledge to competently testify about Par customers. No further reply is required.

PAR Marketed the Spread

23. PAR knew that its customers routinely analyzed the reimbursement spreads by comparing their contract price and the reimbursement prices to gauge their profitability. *Id.* at 123:22-124:18.

<u>PAR'S RESPONSE TO PARAGRAPH 23</u>: Par disputes that its customers' business practices are material to plaintiffs' motion. Notwithstanding the immateriality of Paragraph 23, Par does not dispute that Ms. Trendowicz's testimony is consistent with Paragraph 23 to the extent Paragraph 23 refers to certain customers of Par.

PLAINTIFFS' REPLY TO STATEMENT #23:

Par does not dispute the Statement but says it is immaterial. Par's assertion that its customers' business practices are not material is incorrect. Par's knowledge that its customers gauged profitability by analyzing spread between reimbursement prices (AWPs/WACs/FULs) and actual prices supports plaintiffs' position that Par's reporting and control of its false AWPs and WACs was purposeful, intentional and knowing.

24. PAR knew that AWP was used by its customers to determine profitability between their price and the reported AWP for PAR drugs. See Deposition of Julie Trendowicz dated 9/25/07 ("Trendowicz 9/25/07 Dep.") (Exhibit M) at 61:8-62:21. Pharmacy Benefit Managers (PBMs) like Caremark and Express Scripts purchased drugs from manufacturers, including PAR, based on negotiations expressed as a percentage off of AWP. See Trendowicz 4/1/09 Dep. (Exhibit D) at 133:19-134:25 (explaining that Caremark had informed PAR that its selling price would need to be at 92% off AWP). PAR knew that the only reason to negotiate off of AWP was to determine what the reimbursement spread on a drug was going to be. Id. at 135:1-10.

PAR'S RESPONSE TO PARAGRAPH 24: Par disputes that the alleged facts relating to AWPs are material to plaintiffs' motion, because CMS did not consider AWPs in setting FULs. See Defs.' 56.1 Stmt., at ¶ 34. Par further disputes that its customers' business practices are material to plaintiffs' motion. Notwithstanding the immateriality of Paragraph 24, Par does not dispute that Ms. Trendowicz's testimony is consistent with the first two sentences of Paragraph 24, but Par disputes plaintiffs' characterization of Ms. Trendowicz's testimony in the third sentence of Paragraph 24. As Ms. Trendowicz testified: "Q. Okay. And is there any reason why this transaction would be framed in terms of a percent off of AWP other than to allow the parties to the transaction to figure out what the reimbursement spread is going to be on the drug? *** A. I don't know." Boone Decl., Exh. F (Deposition of Julie C. Trendowicz, April 1, 2009, at 135:1-7).

PLAINTIFFS' REPLY TO STATEMENT #24:

Par does not dispute that AWP was used by its customers to determine profitability between their price and the reported AWP for PAR drugs and that PBMs purchased Par drugs based on negotiations expressed as a percentage off of AWP, but says it is immaterial. Par disputes the third sentence on the grounds that plaintiffs' mischaracterized Ms. Trendowicz's testimony. To the contrary, it is Par who is mischaracterizing the testimony. Plaintiffs stand by their citation of Ms. Trendowicz, whose testimony reads in its entirety: "Q. Okay. And is there any reason why this transaction would be framed in terms of a percent off of AWP other than to allow the parties to the transaction to figure out what the reimbursement spread is going to be on the drug? * * * A. I don't know. Q. (BY MR. WINTER) You can't think of any can you?

A. No." Trendowicz 4/1/09 Dep. (Exhibit D) at 135:1-10 (emphasis added).

Par's Response that AWP prices are not material to plaintiffs' motion is incorrect. *See* Plaintiffs' Reply to Statement #6, which is incorporated herein.

Responding further, Par's Response that its customers' business practices are not material is incorrect. *See* Plaintiffs' Reply to Statement #23, which is incorporated herein.

25. PAR knew that its customers determined profitability based on reimbursement spreads and often informed PAR that its competitors had better reimbursement spreads in order to give PAR an opportunity to compete with them. *Id.* at 122:5-123:2.

PAR'S RESPONSE TO PARAGRAPH 25: Par disputes that its customers' business practices are material to plaintiffs' motion. Notwithstanding the immateriality of Paragraph 25, Par does not dispute that (i) Ms. Trendowicz testified that she knew that customers would look at the difference between AWPs and contract prices and (ii) on at least one occasion, one of Par's customers (ESI) informed Par that it had received a competitive offer for a particular product (imipramine) that included a larger discount off of AWP. Except as noted, plaintiffs have not provided an evidentiary basis for the assertions that Par "knew that its customers determined profitability based on reimbursement spreads and often informed PAR that its competitors had better reimbursement spreads in order to give PAR an opportunity to compete with them," because the cited

testimony does not support those asserted facts. Specifically, Ms. Trendowicz's testimony was limited to a single communication, which was authored by a third party and related to a single product that is not at issue in plaintiffs' motion.

PLAINTIFFS' REPLY TO STATEMENT #25:

The Parties agree that Ms. Trendowicz testified that she knew that Par customers would look at the difference between AWPs and contract prices. The parties also agree that ESI informed Par that it had a competitive offer that included a larger discount off AWP. Beyond that, Ms. Trendowicz testimony speaks for itself as follows:

Q. (BY MR. WINTER) Ms. Trendowicz, you acknowledged in the deposition that you gave in the Massachusetts litigation that you knew that your customers, whether you were at Par or in your prior positions, routinely would analyze the profitability to them on purchases by looking at their AWPs, the AWP on the product they were buying, and the contract price.

MR. DUEFFERT: Objection to form.

Q. (BY MR. WINTER) Do you remember doing that --

A. Yes.

Q. -- taking -- and as you sit here today, you -- you're aware and you were aware during the entire time that you were at Par that customers would routinely analyze the reimbursement spread that they received by looking at the reimbursement benchmarks, such as AWP, and their contract price and gauging the profit they would get from third-party reimbursement, correct?

MR. DUEFFERT: Objection to form.

A. Yes.

Id. at 124:22-125:18

Par cannot reasonably argue that Ms. Trendowicz's testimony was limited to a single communication with a Par customer and related to one product that is not at issue in plaintiffs' motion. The testimony, on its face, is more general than that. (See above) Nor can Par reasonably dispute that Ms. Trendowicz, as VP for National Accounts (1998) and Vice President

of Sales (1999-2007), has sufficient experience and personal knowledge to competently testify about Par customers generally.

Plaintiffs do not maintain that Imipramine is a drug at issue on this motion, however, the record evidence serves to illustrate that Par customers received competitive offers that had larger discounts off AWP and thereafter asked Par to compete based on spread.

Responding further, Par's Response that its customers' business practices are not material is incorrect. *See* Plaintiffs' Reply to Statement #23, which is incorporated herein.

26. PAR knew that when a MAC or FUL was in place that its customers used the MAC/FUL to determine the profit spread between its cost for PAR drugs and the MAC/FUL. See PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 185:21-187:11; Exhibit N (PAR 30(b)(6)(DiMaio) 5/6/08 Dep. Exhibit 41 (Mail order pharmacy CFI of New Jersey's Request for Generic Contract Proposal for 1999-2000 showing the spread between the MAC or AWP and PAR's bid price)).

PAR'S RESPONSE TO PARAGRAPH 26: Par disputes that its customers' business practices are material to plaintiffs' motion. Par further disputes that plaintiffs have provided an evidentiary basis for the facts set forth in Paragraph 26, because the testimony and document cited do not support the asserted facts with respect to Par's knowledge of the conduct of its customers. Rather, the cited testimony and document merely establish that one customer (CFI) sent to Par a document that included a column for "Mac" and that this column appears to include data provided by the customer.

PLAINTIFFS' REPLY TO STATEMENT #26:

Plaintiffs stand by their Statement and the cited record evidence which speaks for itself and shows that the CFI Request for Generic Contract Proposal for 1999-2000 (Exhibti N): (i) stated, "Please provide pricing for all products your firm has to offer including NDC Number, MAC Price, AWP, Proposed Cost, and Minimum Quatities"; and, (ii) included a column for "Spread". Par cannot reasonably dispute that its customers used the MAC/FUL to determine the profit spread between its cost for PAR drugs and the MAC/FUL when PAR in fact marketed this to its customers and admits its customers informed Par of their spread from the MAC/FUL. *See*

Plaintiffs' Reply to Statements #27 and #28, which are incorporated herein.

Responding further, Par's Response that its customers' business practices are not material is incorrect. *See* Plaintiffs' Reply to Statement #23, which is incorporated herein.

27. PAR marketed drugs based on the reimbursement spread between the price to pharmacies and reimbursement based upon the FUL. See e.g., Exhibit O (PAR 30(b)(6)(DiMaio) 5/6/08 Dep. Exhibit 34 (PAR presentation titled, "McKesson/Par Penicillin Opportunity" showing that pharmacies could make a 69% profit from the FUL (HFCA/MAC))).

PAR'S RESPONSE TO PARAGRAPH 27: Par disputes Paragraph 27. Specifically, Par disputes that Par's marketing practices are material to plaintiffs' motion. In addition, plaintiffs' do not provide an evidentiary basis for the facts set forth in Paragraph 27, because the document cited does not support those facts. The cited document does not indicate that it was presented to McKesson, nor does it establish that "Par marketed drugs based on the reimbursement spread between the price to pharmacies and reimbursement based upon the FUL." As Mr. DiMaio testified: "Q. So it's showing McKeeson (sic) how McKeeson's (sic) customers can make money off the spread because they can sell a Par product at far below the federal upper limit. Right? * * * A. No, I think that's wrong. I think that's wrong. I am not sure. It doesn't show what the retailers are selling this product for. It only talks about cost." Boone Decl., Exh. B (DiMaio 5/6/08 Dep. at 174:19-175:6). Moreover, the document cited refers exclusively to a single customer (McKesson) and a single product (amoxicillin) that is not at issue in plaintiffs' motion.

PLAINTIFFS' REPLY TO STATEMENT #27:

Plaintiffs stand by their Statement. The cited record evidence speaks for itself. The slide presentation titled "McKesson/Par Penicillin Opportunity" contains a slide "Amoxicillin Profit Analysis" with the bullet point "Wholesale v. Retail Analysis" which clearly illustrates a scenario where the wholesaler cost is \$1.50, the wholesale sell price/retail cost is \$1.65, the FUL (HCFA MAC) is \$2.78 and the resulting profit from the between the FUL and retail cost is 69%. *See* Exhibit O.

Par's dispute that the "McKesson/Par Penicillin Opportunity - Par Pharmaceuticals" document does not indicate it was presented to McKesson is meaningless. It is indisputable that

Par prepared the document and its title speaks for itself. Further responding, Mr. DiMaio testified as if the document was presented to McKesson. Regardless, the material fact is that the document again shows that Par knew that its customers wanted to see the spread between reimbursement based on FUL and the actual price.

Plaintiffs do not maintain that amoxicillin is a drug at issue on this motion, however, the record evidence establishes that Par showed McKesson how its pharmacy customers could make a profit on Par drugs (in the cited example, a 69% profit), which is material to plaintiffs' motion.

Par's Response that its marketing practices are not material is incorrect. Par's knowledge that its customers gauged profitability by analyzing spread between reimbursement prices (AWPs/WACs/FULs) and actual prices and the fact that Par marketed the spread supports plaintiffs' position that Par's reporting and control of its false AWPs and WACs was purposeful, intentional and knowing.

28. Nick DiMaio testified that it was common that customers would request PAR to lower prices or increase spread as it related to their reimbursement and when a MAC/FUL was in place. See PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 57:5-14, 60:18-62:12; Exhibit P (PAR 30(b)(6)(DiMaio) 5/6/08 Dep. Exhibit 43 (5/11/03 spreadsheet identifying PAR drugs and when a MAC/FUL was in place and requesting better pricing or an increase in their spread below the MAC/FUL)).

PAR'S RESPONSE TO PARAGRAPH 28: Par disputes that its customers' business practices are material to plaintiffs' motion. Par further disputes Paragraph 28 to the extent that it mischaracterizes Mr. DiMaio's testimony. Mr. DiMaio testified that it was "common for customers to say we're not making --we can't get reimbursed properly based on your cost. That's common." Boone Decl., Exh. B (DiMaio 5/6/08 Dep. at 62:9-12). Par further disputes any suggestion that such a request by a customer would impact Par's pricing practices. As Mr. DiMaio testified: "Q. Is it important to Par that there be a spread between the MAC or the acquisition or contract price of a Par drug? *** A. For Par, we base our pricing on competitive conditions in the marketplace so we don't look at, you know, the limits on reimbursement don't affect the way we price drugs. We are commodity driven. The market determines our pricing for our drugs. . . . A. These, typically what happens, these kinds of comments are generated from the field where a pharmacy would say, you know, for some reason your pricing is below the MACs allowable cost. So typically it's common for feedback from

customers saying you are pricing your product at X and the MAC is, you know, X minus something. So these comments are consistent with what we would get from the field, and of course, then, we would have to – we would address that and say you may want to talk to your -- the companies, Medicaid, insurance payers, because there seems to be a problem. You are not getting reimbursed to cover the cost of these drugs." *Id.*, Exh. B (DiMaio 5/6/08 Dep. 57:19-58:2; 61:12-62:3).

PLAINTIFFS' REPLY TO STATEMENT #28:

Plaintiffs stand by their Statement. The cited record evidence speaks for itself. The May 11, 2003 spreadsheet identifies PAR drugs, Bid Price, Bid Price Needed, Rebate, Annual Forecast and Comments. *See* Exhibit P. In four situations, the Comments identify the State MAC and state "Need better spread between cost and reimbursement". *Id.* In all four of these instances the Bid Price is less than the identified State MAC. *Id.* In seven instances the Bid Price is higher than the State MAC identified in the Comments with either the statement "Got to get us below MAC" or "need price below MAC". *Id.*

Par disputes the above Statement only to the extent it mischaracterizes Mr. DiMaio's testimony. This means Par does not dispute the Statement. It is Par who mischaracterizes Mr. DiMaio testimony by only citing Mr. DiMaio's answers out of context without the questions. The testimony of Mr. DiMaio cited by Par (and also cited by plaintiffs) does not contradict the document and in fact establishes that this document was typical and common. Responding further, the testimony of Mr. DiMaio was not limited to just the situation where a customer requested a price lower than a MAC, but included the situation where a greater spread was requested:

- Q. Well, these comments refer not to the state lowering its MAC, but that Par needs to have a better spread between cost and reimbursement; correct?
- MR. DUEFFERT: Objection to form.

 A. That's what I'm saying. That would be common for customers to say we're not making --

we can't get reimbursed properly based on your cost. That's common.

PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 62:4-12.

Responding further, Par's Response that its customers' business practices are not material is incorrect. *See* Plaintiffs' Reply to Statement #23, which is incorporated herein.

29. When a PAR product was not subject to a MAC or FUL, PAR marketed the fact that the customer could receive higher reimbursement. See Tredowicz 4/1/09 Dep. (Exhibit D) at 284:1-291:22, 295:25-298:12. PAR marketed the fact that its 20mg Fluoxitine Tablets were not subject to a MAC/FUL in order to get business away from its competitors who were selling 20mg Fluoxitine Capsules that were subject to a MAC/FUL. Id.

<u>PAR'S RESPONSE TO PARAGRAPH 29</u>: Par disputes that its marketing practices and its practices with respect to drugs not subject to a FUL are material to plaintiffs' motion. In addition, Par disputes the facts set forth in Paragraph 29 and disputes plaintiffs' characterization of Ms. Trendowicz's testimony, which was limited to a single product not at issue in plaintiffs' motion (fluoxetine), and which was limited to certain customers.

PLAINTIFFS' REPLY TO STATEMENT #29:

Par cannot reasonable dispute the Statement. Ms. Trendowicz's testimony speaks for itself:

- Q. (BY MR. WINTER) Well, you do know that from time to time government-funded programs such as the Medicaid program will set MACs or federal upper limits when there is more than one generic competitor in the market on a given drug, right?
 - A. Yes.
- Q. And what Mr. Johnston is pointing out to his colleagues within Albertsons is that, hey, Par doesn't have any competition on this 20-milligram tablet. Par is single source. And as you just explained to me, what that means to you is, hey, he's pointing out the fact that there's no MAC, so that means that reimbursement on Par's product is not going to be constrained by the MAC, right?

MR. DUEFFERT: Objection to form.

- A. At that particular time, yes.
- Q. (BY MR. WINTER) And, in fact, that was part of Par's proposal when it was reaching out to its

customers and potential customers trying to get them to convert from the competitor's capsules to Par's tablets. Par would point out the fact that there was no MAC on Par's tablets, right?

MR. DUEFFERT: Objection to form.

- A. I don't remember if they pointed that out. I know at the beginning we were pointing out the price -- the savings between us and the Barr product for the six months' exclusivity period.
- Q. (BY MR. WINTER) Well, you are talking about now just the net price, right, the contract price?
 - A. Right.
- Q. Didn't Par also point out for its customers that not only is there a savings because Par has more competitive or -- or less expensive net pricing, there is also a reimbursement component that increases the profitability for the customer because the Par product doesn't have a MAC?
 - A. Well, that --

MR. DUEFFERT: Objection to form.

- A. That was the offer we are -- we're putting out there now out to Scott Johnson, yes.
- Q. (BY MR. WINTER) Okay. So that is something you pointed out to him?

MR. DUEFFERT: Objection to form.

- A. Well, I don't know if we pointed it out to him or he figured it out. You know, I don't -- I don't know if I told him that.
- Q. (BY MR. WINTER) Don't you recall being involved in presentations to customers?
- A. I know -- I know he knew we were single sourced.
- Q. But my question, ma'am, is don't you recall being part of presentations to customers, for example, Walgreens, where you would point out to the customer that, hey, our Par product is single source, it's not MAC'd, so you are going to get more in reimbursement spread on our product than you would on the competitor product which is MAC'd?

MR. DUEFFERT: Objection to form.

- A. I think we had a presentation like that, yes.
- Q. (BY MR. WINTER) Okay. So you do recall having engaged in conversations such as I've just described with some of your customers?
 - A. Yes.

Tredowicz 4/1/09 Dep. (Exhibit D) at 295:25-298:12.

Plaintiffs do not maintain that fluoxetine is a Par drug at issue on this motion, however, the record evidence establishes that Par was well aware how a MAC or FUL impacted its customers' reimbursement, which is material to plaintiffs' motion.

Responding further, Par's Response that it's marketing practices and practices with respect to drugs not subject to FUL are not material is incorrect. Par's knowledge that its customers gauged profitability by analyzing spread between reimbursement prices (AWPs/WACs/FULs) and actual prices and the fact that Par marketed the spread supports plaintiffs' position that Par's reporting and control of its false AWPs and WACs was purposeful, intentional and knowing.

30. PAR was not aware of the 2003 OIG Guidelines. See PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 38:5-18.

PAR'S RESPONSE TO PARAGRAPH 30: Par disputes that the 2003 OIG Guidelines are material to plaintiffs' motion. Notwithstanding the immateriality of Paragraph 30, Par does not dispute that Mr. DiMaio testified that he, personally, was not aware of the 2003 OIG Guidelines.

PLAINTIFFS' REPLY TO STATEMENT #30:

The parties agree that Mr. DiMaio, Executive Vice President of Sale & Marketing for Par, testified that he was not aware of the 2003 OIG Guidelines.

Responding further, the 2003 OIG Guidelines are indisputably material to plaintiffs' motion insofar as they confirm statutory requirements and common law principles governing drug manufacturer price reporting.

Par's AMPs

31. At all times, from 1997 to 2005, PAR has calculated on a quarterly basis the average manufacturer's price ("AMP") for all its products as required by the federal rebate statute. See PAR 30(b)(6)(DiMaio) 5/6/08 Dep. (Exhibit B) at 108:18-22.

<u>PAR'S RESPONSE TO PARAGRAPH 31</u>: Par does not dispute the facts set forth in Paragraph 31.

PLAINTIFFS' REPLY TO STATEMENT #31:

No further reply is required.

Dated: June 30, 2009

Respectfully submitted,

KIRBY McINERNEY, LLP

825 Third Avenue New York, New York 10022 (212) 371-6600

/s/ Joanne M. Cicala_____

By: Joanne M. Cicala

James P. Carroll Jr. Jocelyn R. Normand

Kathryn Allen

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Counsel for the County of Orange

CERTIFICATE OF SERVICE

I, James P. Carroll Jr., hereby certify that I caused a true and correct copy of the foregoing PLAINTIFFS' REPLY LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO PAR PHARMACEUTICALS COMPANIES, INC., AND PAR PHARMACEUTICAL, INC., to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: June 30, 2009

James P. Carroll, Jr.
Kirby McInerney LLP
825 Third Avenue, 16th Floor
New York, NY 10022
(212) 371-6600

EXHIBIT A

Case 1:01-cv-12257-PBS

Document 4690-2

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UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL NO. 1456 Civil Action No. 01-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO:

The City of New York v. Abbott Labs., et al.)
(S.D.N.Y. No. 04-CV-06054))
County of Suffolk v. Abbott Labs., et al.)
(E.D.N.Y. No. CV-03-229))
County of Westchester v. Abbott Labs., et al.)

(S.D.N.Y. No. 03-CV-6178)

County of Rockland v. Abbott Labs., et al. (S.D.N.Y. No. 03-CV-7055)

County of Dutchess v. Abbott Labs., et al.

(S.D.N.Y. No. 05-CV-06458)

County of Putnam v. Abbott Labs., et al.

(S.D.N.Y. No. 05-CV-04740)

County of Washington v. Abbott Labs., et al.) (N.D.N.Y. No. 05-CV-00408)

County of Rensselaer v. Abbott Labs., et al.

(N.D.N.Y. No. 05-CV-00422)

County of Albany v. Abbott Labs., et al. (N.D.N.Y. No. 05-CV-00425)

[Caption Continues on Next Page]

[PROPOSED] CASE MANAGEMENT ORDER NO

September 4, 2007

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CI CITY ALL VIII I	
County of Warren v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00468))
County of Greene v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00474))
County of Saratoga v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00478))
County of Columbia v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00867)	í
Essex County v. Abbott Labs., et al.	í
(N.D.N.Y. No. 05-CV-00878)	í
County of Chenango v. Abbott Labs., et al.	í
(N.D.N.Y. No. 05-CV-00354)) \
County of Broome v. Abbott Labs., et al.	΄
(N.D.N.Y. No. 05-CV-00456)	,
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County of Onondaga v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00088))
County of Tompkins v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00397))
County of Cayuga v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00423))
County of Madison v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00714))
County of Cortland v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00881))
County of Herkimer v. Abbott Labs. et al.)
(N.D.N.Y. No. 05-CV-00415))
County of Oneida v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00489))
County of Fulton v. Abbott Labs., et al.)
(N.D.N.Y. No. 05-CV-00519))
County of St. Lawrence v. Abbott Labs., et a	ĺ)
(N.D.N.Y. No. 05-CV-00479)	í
County of Jefferson v. Abbott Labs., et al.	í
(N.D.N.Y. No. 05-CV-00715)	í
County of Lewis v. Abbott Labs., et al.	í
(N.D.N.Y. No. 05-CV-00839)	í
County of Chautauqua v. Abbott Labs., et al.	Ś
(W.D.N.Y. No. 05-CV-06204)	· /
County of Allegany v. Abbott Labs., et al.	1
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County of Cattaraugus v. Abbott Labs., et al	7
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•)
(W.D.N.Y. No. 05-CV-06206))

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County of Wayne v. Abbott Labs., et al.
(W.D.N.Y. No. 05-CV-06138)
County of Monroe v. Abbott Labs., et al.
(W.D.N.Y. No. 05-CV-06148)
County of Yates v. Abbott Labs., et al.
(W.D.N.Y. No. 05-CV-06172)
County of Niagara v. Abbott Labs., et al.
(W.D.N.Y. No. 05-CV-06296)
County of Seneca v. Abbott Labs., et al.
(W.D.N.Y. No. 05-CV-06370)
County of Orleans v. Abbott Labs., et al.
(W.D.N.Y. No. 05-CV-06371)
County of Ontario v. Abbott Labs., et al.
(W.D.N.Y. No. 05-CV-06373)
County of Schuyler v. Abbott Labs, et al.
(W.D.N.Y. No. 05-CV-06387)
County of Steuben v. Abbott Labs., et al.
(W.D.N.Y. No. 05-CV-06223)
County of Chemung v. Abbott Labs., et al.
(W.D.N.Y. No. 05-CV-06744)
County of Ulster v. Abbott Labs, et al
(N.D.N.Y. Case No. 06-CV-0123)
County of Wyoming v. Abbott Labs, et al.
(W.D.N.Y. No. 05-CV06379)
AND
County of Nassau v. Abbott Labs., et al.
(E.D.N.Y. No. 04-CV-5126)
County of Orange v. Abbott Labs., et al.,
(S.D.N.Y. No. 07-CV-2777)
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Saris, U.S.D.J.

WHEREAS, the Judicial Panel for Multidistrict Litigation has transferred to this

Court for pre-trial purposes numerous complaints brought by individual counties of the State of

and the new exhibits discussed below. Each plaintiff County in the FACC is deemed to have sued each defendant for statute of limitations purposes as of the date on which that County filed its original complaint in the transferor court or the date on which the plaintiff County joined in any consolidated NY County pleading, whichever is earlier. However, each plaintiff County is deemed to be proceeding against only those defendants named in the caption of the complaint filed in the transferor Court.

- 2. On or before September 30, 2007, Plaintiffs shall file amended Exhibits B to the FACC that contain the information appearing at Exhibits B-1 and D to the Declaration of Joanne M. Cicala dated July 11, 2007 ("Cicala Declaration"); provided however, that said Exhibits to the Cicala Declaration shall be further amended to create a new FACC Exhibit B-1 as follows:
- (a) plaintiffs shall delete all NDCs relating to the 348 new drugs identified in Cicala Declaration Exhibit A-2;
- (b) plaintiffs shall allege a weighted average, or typical, price for each drug calculated on a reasonable good faith basis consistent with ¶ 5 of this Court's July 30, 2007 order and prior opinions.
- c) any NDC for which the percentage difference between the weighted average, or typical, wholesale price alleged by plaintiffs and the published Average Wholesale Price ("AWP") for that NDC is 30% or less shall be moved from FACC Exhibit B-1 and placed in an amended FACC Exhibit B-2;
- (d) Amended FACC Exhibits B-1 and B-2 shall identify which NDCs are dual channel, i.e. NDCs that were dispensed either by a physician and reimbursed by New

York Medicaid based on actual cost or by a pharmacy provider and reimbursed by New York Medicaid based on AWP or FUL by the Counties that are parties to the FACC, during the time period covered by the FACC.

- 2. On or before November 30, 2007, Orange County shall file new FACC Exhibits B-3 and B-4 that shall identify the Orange-Only Defendants and shall contain the same information and format as new FACC Exhibits B-1 and B-2, but which exhibits shall contain information limited to the NDCs of the Orange-Only Defendants in the original Orange County complaint. The parties agree that this deadline may be extended if, notwithstanding Orange County's best efforts, there is a delay in the production of the necessary data that results from events beyond Orange's control. With the addition of Exhibits B-3 and B-4, the FACC shall be deemed Orange County's amended complaint. No discovery shall be sought from any of the Orange-Only Defendants until, at the earliest, after that defendant has filed an answer, as discussed in paragraph 8.
- 4. Discovery is stayed as to all NDCs appearing in new FACC Exhibits B-2 and B-4 until such time as the plaintiffs submit an expert affidavit providing a good faith basis for a 20-25% spread threshold.
- 5. The Court adopts the following procedures for targeted discovery on drugs subject to Federal Upper Limits ("FULs") and that were paid for by New York Medicaid on the basis of such FULs
- (a) on or before October 1, 2007, plaintiffs and defendants shall each as a group identify five (5) drugs by chemical name for a total of ten drugs (the "Designated FUL Drugs");

- (b) plaintiffs and defendants shall engage in such party and third-party discovery as they deem relevant to the prosecution and defense of the claims in the FACC relating to FULs generally; however, there shall be no discovery on particular drugs or NDCs subject to and paid by New York Medicaid based on FULs other than those relating to the Designated FUL Drugs and for such Designated FUL Drugs, discovery is limited to the period 1997 to 2005;
- (c) fact discovery pursuant to this paragraph shall be completed on or before March 31, 2008;
- (d) plaintiffs shall provide an expert report relating to the Designated FUL Drugs specifically and their FUL allegations generally on or before April 30, 2008 and shall within 30 days thereafter submit their experts for depositions;
- (e) defendants shall provide an expert report relating to the Designated FUL Drugs specifically and their FUL defense generally on or before June 20, 2008 and shall within 30 days thereafter submit their experts for depositions.
- 6. At the conclusion of expert discovery in paragraph 5, the parties shall schedule another status conference with the Court to discuss briefing of summary judgment or other motion practice as to the Designated FUL Drugs, as well as other issues in the NY County Cases.
- 7. Discovery on all drugs in new FACC Exhibits B-1 and B-3, and on all other issues in the FACC generally, to the extent not covered by paragraphs 4 and 5 above shall proceed in accordance with the Federal Rules of Civil Procedure and this Court's past Case

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 Management Orders. The Court finds that AWP-based claims that accrued prior to



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Filed 09/06/2007

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substantial statutes of limitations defense and accordingly limits the time period for discovery on drugs covered in this paragraph seven to the period $\frac{1997}{2005}$.

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8. Except for (1) the Orange-Only Defendants and (2) any defendant named in the FACC that has an individual motion to dismiss outstanding or has previously entered into a stipulation for an extension of time to answer the FACC, defendants shall answer the FACC on or before October 26, 2007. Any defendant whose motion to dismiss remains pending shall, if the motion is not granted, answer the FACC within thirty (30) days of the Court's order disposing of the motion. Although not bound by the Court's prior decisions in the NY County Cases, the Orange-Only Defendants may file motions to dismiss in lieu of answering the FACC only if they believe there are meritorious arguments not previously addressed in the Court's decisions in the NY County Cases and that are unique to them. Any such motions by the Orange-Only Defendants shall be filed no later than 30 days after Orange files Exhibits B-3 and B-4 as described above. If any such Orange-Only motions are denied, the Orange-Only defendant shall answer the FACC within thirty (30) days of the Court's order on such motions. If the Orange-Only Defendants elect to answer the FACC in lieu of moving for dismissal, such answers shall be filed no later than 30 days after Orange files Exhibits B-3 and B-4 as described above.

Patti B. Saris, U.S.D.L.

New York and by the City of New York against pharmaceutical manufacturers relating to prices for prescription drugs under New York Medicaid (collectively, the "NY County Cases"); and

WHEREAS, New York City and 41 Counties, represented by Kirby McInerney & Squire, LLP and Nassau County represented by Milberg Weiss LLP have joined in a First Amended Consolidated Complaint ("FACC"), which was filed on June 8, 2007; and

WHEREAS, Orange County, represented by a Levy Phillips & Konigsberg LLP, has asked that it be joined as a plaintiff in the FACC; and

WHEREAS, all defendants named in the FACC moved to dismiss as to issues common to them and certain individual defendants have made supplemental motions to dismiss the FACC for additional reasons; and

WHEREAS, the Court, after hearing argument on defendants' common motion to dismiss the FACC on July 26, 2007, issued an order dated July 30, 2007 granting in part and denying in part that motion; and

WHEREAS the Court on July 26, 2007 directed the parties to adopt certain case management procedures for the orderly administration of the NY County Cases.

NOW THEREFORE, it is ORDERED, as follows:

1. Orange County is added to the FACC as a plaintiff. Any defendant named in the original Orange County complaint but not previously named in the FACC shall be made a defendant in the FACC, but only as to the claims of Orange County and neither the City of New York nor any other County in the FACC shall be deemed to have sued such defendants (the "Orange-Only Defendants"). Within the timeframes set forth below, all plaintiffs shall file and serve via LEXIS/NEXIS a FACC that contains no changes other than to include Orange County

EXHIBIT B

Woodcliff, NJ

		Page 1
1	UNITED STATES DISTRICT COURT	J
2	FOR THE DISTRICT OF MASSACHUSETTS	
3	X	
4	IN RE PHARMACEUTICAL INDUSTRY) MDL NO. 1456	
5	AVERAGE WHOLESALE PRICE LITIGATION) Master File No.	
6	X 01-12257-PBS	
7	THIS DOCUMENT RELATES TO:) Judge Patti B.	
8	City of New York, et al. v. Abbott) Saris	
9	Laboratories, et al. Civil Action)	
10	No. 04-cv-06054 et al.)	
11	X	
12	- and -	
13	COMMONWEALTH OF KENTUCKY	
14	FRANKLIN CIRCUIT COURT - DIV. 1	
15	X	
16	COMMONWEALTH OF KENTUCKY ex rel.) CIVIL ACTION NO.	
17	JACK CONWAY, ATTORNEY GENERAL) 04-CI-1487	
18	v.)	
19	ALPHARMA USPD, INC., et al.)	
20	X	
21	VIDEOTAPED DEPOSITION OF PAR PHARMACEUTICALS	
22	2 (NICK DIMAIO), MAY 6, 2008	

Woodcliff, NJ

Page 202 Page 204 National Drug Code; correct? (Discussion held off the record.) 1 1 2 Q. I am placing in front of you what's 2 A. Yes. 3 been marked as Exhibit No. 61 which is a copy of 3 Q. The first five digits tend to be what our notice of deposition in the New York are called the labeler code; is that correct? 4 4 5 litigation. 5 A. That's correct. 6 O. Is 49884 the Par labeler code? 6 Have you seen this particular document 7 before? 7 A. Yes. 8 (Exhibit DiMaio 061, Notice of 8 MS. CICALA: I want to note for the deposition in the New York litigation, marked for 9 9 record drugs amoxicillin and penicillin are 10 identification.) 10 included as at issue drugs in the New York A. Yes, I have seen this. litigation and I note this in response to 11 11 Q. Do you understand you are here today to counsel's objection this morning with regard to 12 12 testify on certain of the subjects that are Mr. Archibald's questions that concerned those 13 13 drugs. Counsel had noted those drugs were not at contained in this particular document? 14 14 15 A. Yes, I do. 15 issue in Kentucky. I take no position on whether they are at issue in Kentucky. I simply note --Q. Which subjects do you understand that 16 16 you are here to testify on today? Or if it's that they are at issue in New York. 17 17 18 easier, which subjects are you not here to 18 MR. DUEFFERT: I am looking through testify on? 19 this list, counsel, that's been marked as DiMaio 19 20 A. I don't remember the numbers, but it's 20 62. I am trying to compare it with Exhibit B 27 of the complaint. For instance, I am looking for typically anything to do with sales and 21 21 the word Capoten and I don't actually see that 22 marketing. Anything with calculations of A and P 22 Page 203 Page 205 I am not the expert on. 1 actually in B 27 of the complaint which is the 1 2 MR. DUEFFERT: For the record, counsel, 2 only version I have seen before. 3 Par has designated him to address all the topics 3 I'll just note to accept this list is in this notice, for the record. not consistent with what was provided to us as 4 4 5 MS. CICALA: Thank you. 5 Exhibit B 27, the complaint, I'll object. We'll mark as Exhibit 62 a document MS. CICALA: It is certainly our intent 6 6 that Exhibit 62 reflect Exhibit B of our that I will represent to you, Mr. DiMaio, is a 7 7 8 list of the Par drugs that are at issue in our 8 complaint. 9 litigation, and for counsel's benefit, these are 9 Q. Mr. DiMaio, your responsibilities at the drugs with a spread of greater than 30 Par, as you testified at length, were primarily 10 10 11 percent in the New York Exhibit B to our first 11 in the arenas of sales and marketing; correct? amended consolidated complaint. A. That's correct. 12 12 13 (Exhibit DiMaio 062, List of the 13 Q. What is marketing? 14 Par drugs, marked for identification.) 14 A. At Par Pharmaceuticals or --Q. Just generally, Mr. DiMaio, do you 15 15 Q. To you, in your experience. recognize the drugs on Exhibit 62 to be drugs 16 16 MR. DUEFFERT: Objection to form. that were either manufactured or marketed by Par? A. The sales and marketing on the generic 17 17 side are pretty tightly-knit together since we 18 A. Yes, I do. 18 O. You are familiar with what the -- with are competing in a commodity market. So 19 19 the acronym NDC? traditionally, marketing would be anything with 20 20 price, promotion. Pricing, promotion, I forgot 21 A. Yes, I am. 21 my MBA course, but basically all the support 22 Q. It appears in the -- stands for 22

52 (Pages 202 to 205)